January 16, 2015

SENATE BILL No. 66

DIGEST OF SB 66 (Updated January 14, 2015 11:40 am - DI ck)

Citations Affected: IC 16-42; IC 35-52.

Synopsis: Investigational treatments for terminal illnesses. Permits use of investigational treatments for certain individuals with terminal illnesses.

Effective: July 1, 2015.

Long

January 6, 2015, read first time and referred to Committee on Rules & Legislative Procedure.
January 15, 2015, amended; reassigned to Committee on Health & Provider Services.

January 16, 2015

First Regular Session 119th General Assembly (2015)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

SENATE BILL No. 66

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-42-26 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]:

Chapter 26. Investigational Treatments

Sec. 1. As used in this chapter, "eligible individual" means an individual whose treating physician, licensed under IC 25-22.5, determines and documents all of the following:

(1) The individual has a terminal illness.

(2) The individual has considered all treatment options for the terminal illness that are currently approved by the federal Food and Drug Administration.

(3) The treating physician has recommended an investigational treatment for the individual's terminal illness.

(4) The individual, or the parent or personal representative of the individual, has given informed consent for the individual to receive the investigational treatment.

Sec. 2. As used in this chapter, "informed consent" means a written document signed by an individual or the individual's parent or personal representative, the individual's treating physician, and a witness, that includes all of the following:

(1) An explanation of currently approved treatments for the individual's terminal illness.

(2) Confirmation that the individual concurs with the treating physician that currently approved treatments are unlikely to prolong the individual's life.

(3) Clear identification of the specific investigational treatment that the individual wishes to undergo.

(4) A description of all potential outcomes of the investigational treatment, and the most likely outcome for the individual:

(A) including the possibility that:

(i) unanticipated or different symptoms; and

(ii) death;

may result from the investigational treatment; and

(B) based on the treating physician's knowledge of the:

(i) investigational treatment; and

(ii) individual's condition.

(5) A statement that a third party payer is not, unless otherwise required by law or contract, obligated to pay for:

(A) investigational treatment; or

(B) care that is required as a result of the investigational treatment.

(6) A statement that the individual's:

(A) eligibility for hospice care may be withdrawn if the individual begins the investigational treatment; and

(B) hospice care may be reinstated if the investigational treatment ends and the individual meets the eligibility requirements for hospice care.

(7) A statement that the individual understands that:

(A) the individual is liable for all expenses resulting from the investigational treatment; and

(B) the liability extends to the individual's estate;

unless a contract between the individual or the individual's parent or personal representative and the manufacturer of the investigational treatment provides otherwise.

Sec. 3. As used in this chapter, "investigational treatment" means a drug, biological product, or device:

(1) for which a Phase I clinical trial approved by the federal

Food and Drug Administration has been successfully completed;

(2) that is currently under investigation in a clinical trial approved by the federal Food and Drug Administration; and

(3) for which approval for general use by the federal Food and Drug Administration has not been granted.

Sec. 4. As used in this chapter, "terminal illness" means a progressive disease or medical or surgical condition that:

(1) causes significant functional impairment;

(2) is not considered by the treating physician to be reversible with administration of available treatment that is currently approved by the federal Food and Drug Administration; and

(3) without life sustaining procedures will result in imminent death.

Sec. 5. (a) A manufacturer of an investigational treatment may, but is not required to, make the investigational treatment available to an eligible individual.

(b) A manufacturer of an investigational treatment may provide the investigational treatment to an eligible individual with or without compensation for the:

(1) cost of the investigational treatment; and

(2) costs arising from the use of the investigational treatment.

Sec. 6. (a) This chapter does not require any of the following:

(1) Coverage of an investigational treatment under a health plan that is regulated under IC 27.

(2) Payment by a government agency of the:

(A) cost of an investigational treatment; or

(B) costs arising from the use of an investigational treatment.

(3) Provision of health care services:

(A) by a health care entity that is licensed under this title; and

(B) in connection with an investigational treatment.

(b) A health plan that is regulated under IC 27 or a government health care program may, but is not required to, provide coverage for the:

(1) cost of an investigational treatment; or

(2) costs arising from the use of an investigational treatment.

Sec. 7. (a) The medical licensing board may not revoke the license of, refuse to renew the license of, or take another disciplinary action against a treating physician under IC 25-22.5 based solely on the treating physician's recommendation to an

eligible individual concerning an investigational treatment.

(b) A person that is responsible for Medicare certification of a treating physician may not take action against the treating physician's Medicare certification based solely on the treating physician's recommendation to an eligible individual concerning an investigational treatment.

Sec. 8. (a) An official, employee, or agent of the state who recklessly, knowingly, or intentionally attempts to prevent, or prevents, an eligible individual from receiving an investigational treatment under this chapter commits a Class B misdemeanor.

(b) A licensed health care provider that provides counseling, advice, or a recommendation that is consistent with medical standards of care does not violate subsection (a).

Sec. 9. This chapter does not create a private right of action against:

(1) the manufacturer of an investigational treatment; or

(2) another person involved in the care of an eligible individual receiving an investigational treatment;

if the manufacturer or other person acts in good faith compliance with this chapter and exercises reasonable care.

SECTION 2. IC 35-52-16-90.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 90.4. IC 16-42-26-8 defines a crime concerning investigational treatments.**

COMMITTEE REPORT

Madam President: The Senate Committee on Rules and Legislative Procedure, to which was referred Senate Bill No. 66, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete everything after the enacting clause and insert the following:

(SEE TEXT OF BILL)

and when so amended that said bill be reassigned to the Senate Committee on Health & Provider Services.

(Reference is to SB 66 as introduced.)

LONG, Chairperson